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10/007,267	12/03/2001	Emil C. Gotschlich	040853-01-5029-02	8278

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EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/09/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/007,267

Applicant(s)

GOTSCHLICH, EMIL C.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 22 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 34-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 34-49 are currently pending and under consideration in this application.

#### ***Drawings***

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

#### ***Sequence Compliance***

Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited within the claims and/or specification. It is particularly noted that applicants have not provided SEQ ID NOS for sequences depicted in figure 3-5 either in the figure or in the figure description. See particularly 37 CFR 1.821(d).

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 34-38 and claims 39-49 which depend from claims 34-38 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 34-38 are directed to "A glycosyltransferase" which reads on the product of nature. Amending the claims to read as "An isolated glycosyltransferase..." to show the hand of man would overcome this rejection.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-38 and claims 39-49 which depend therefrom are rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 34-38 recite the phrase "functionally active fragment thereof". It is not clear to the Examiner as to how applicants define "functional activity". A perusal of the specification did not yield a specific definition for the above phrase thus rendering the claims unclear.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roth (US 5,180,674, Jan 19, 1993). Claim 39 is drawn to a composition comprising a glycosyltransferase conjugated to a solid phase support wherein the glycosyltransferase is selected from the group consisting the glycosyltransferases with SEQ ID NO:2 through 6.

Roth et al. teach a method of preparing saccharide compositions by immobilizing glycosyltransferases to a solid support. The reference teaches method of immobilization of glycosyltransferase as well as use of such solid phase supports for making an apparatus for

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glycosyltransferase-catalyzed synthesis of a saccharide composition. However, the reference does not specifically teach the immobilization of glycosyltransferases with SEQ ID NO:2 through 6. With the above reference in hand it would have been obvious to one of ordinary skill in the art, especially one who has isolated a glycosyltransferase capable of synthesizing an oligosaccharide, to immobilize the isolated glycosyltransferase either alone or with other glycosyltransferases and make an apparatus for making oligosaccharides. One of ordinary skill in the art would have been motivated to do so as the solid phase system offers the advantage of continues synthesis of oligosaccharides as well as re-use of enzymes. One of ordinary skill in the art would have a reasonable expectation of success since Roth et al. demonstrate successful immobilization of a similar glycosyltransferase for synthesis of an oligosaccharide.

Therefore, the above invention would have been *prima facie* obvious to one of ordinary skill in the art.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 35-39, 41-44, 46-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-10, 12-16, 18 of U.S. Patent No. 5,798,233. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 35-39, 41-44, 46-49 of the instant application and claims 1-5, 7-10, 12-16, 18 of the reference patent are both directed to glycosyltransferase comprising amino acid sequence with SEQ ID NO:3-6. Functional fragments claimed in the instant claims encompass the polypeptides with SEQ ID NO:3-6 claimed in the reference patent. The portion of the specification (and the claims) in the reference patent that supports the recited amino acid sequences includes several embodiments (functional fragments) that would anticipate the fragments claimed in claims 35-39, 41-44, 46-49 herein. Claims of the instant application listed above cannot be considered patentably distinct over claims 1-5, 7-10, 12-16, 18 of the reference patent when there is specifically recited embodiment that would anticipate mainly claims 35-39 of the instant application. Alternatively, claims 35-39, 41-44, 46-49 cannot be considered patentably distinct over claims 1-5, 7-10, 12-16, 18 of the reference patent when there is specifically disclosed embodiment in the reference patent that supports claims 1-5, 7-10, 12-16, 18 of that patent and falls within the scope of claims 35-39 herein because it would have been obvious to one having ordinary skill in the art to modify

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claims 1-5, 7-10, 12-16, 18 of the reference by selecting a specifically disclosed embodiment that supports those claims i.e., a functional active fragment. One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims 1-5, 7-9 of the reference patent.

### ***Conclusion***

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.

A handwritten signature in black ink, appearing to read "Manjunath N. Rao", is located at the bottom left of the page. The signature is stylized with a large initial 'M' and a long horizontal stroke.